III. REMARKS

A. Status of the Claims

Claims 1-21 are pending. Claim 4 has been amended to correct a typographical omission. New claim 21 has been added. Support for new claim 21 can be found in the specification at page 8, line 28 through page 9, line 10.

B. Rejection of Claim 3 under 35 U.S.C. § 102(b)

In the Office Action, claim 3 was rejected under 35 U.S.C. § 102(b) as being anticipated by W.I.P.O. Publication No. WO 98/00351 to Assargren et al. (hereafter "the Assargren publication"). The Examiner stated that the Assargren publication describes "blister packs that may be used to two drugs, such as a proton pump inhibitor and at least one antibiotic."

This rejection is respectfully traversed. An anticipation rejection under 35 U.S.C. § 102(b) requires that the reference teach each and every limitation of the claim. The Examiner stated that the Assargren publication describes a blister pack that can be used for two drugs such as a proton pump inhibitor in combination with an antibiotic. However, claim 3 recites the combination of an antibiotic and an anti-ulcer drug selected from the group consisting of H2 antagonists, antacids, bismuth compounds, prostaglandins, carbenoxolone and anticholinergic agents. It is noted that proton pump inhibitors are <u>not</u> included in the Markush group of possible anti-ulcer drugs. Accordingly, the Assargren publication does not teach all of the limitations of claim 3 and the Examiner is respectfully requested to remove the anticipation rejection.

C. Rejection of Claims 1-20 under 35 U.S.C. § 103(a)

The Examiner further rejected claims 1 - 20 under 35 U.S.C. § 103(a) as being unpatentable over W.I.P.O. Publication No. WO 88/02342 to Eek (hereafter "the Eek publication"), in view of the United States Patent No. 6,365,184 to Depui et al. (hereafter "the Depui patent"). "

This rejection is respectfully traversed.

According to the Examiner, "the motivation to create the disclosed combination dosage form originates from a desire to give a patient a composition that is convenient to take, leading to greater compliance. As the disclosed invention of Eek is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of omeprazole and diclofenac in accordance with a combination dosage regimen with a reasonable expectation of success."

It is respectfully submitted that the Examiner has failed to set forth the requisite suggestion or motivation to modify the references to arrive at the present invention. In support of this position, the Examiner is directed to M.P.E.P. § 2143.01, pg 2100-127, which states:

"If proposed modification would render the prior art invention being modified <u>unsatisfactory</u> for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *Emphasis added*.

The Depui patent is directed to a <u>single</u> dosage form containing both omeprazole and diclofenac. The present invention is directed to a drug packaging system comprising omeprazole and diclofenac in <u>separate</u> dosage forms. Modification of the Depui patent to arrive at the present invention would render the prior art invention <u>unsatisfactory</u> for its intended purpose as the present invention is directed to separate dosage forms. In fact, the Depui patent affirmatively supports the position that such modification will render the invention described therein unsatisfactory at column 2, lines 36-38, stating that "administration of two or even more different tablets to the patient is <u>not</u> convenient or <u>satisfactory</u> to achieve the most optimal results." Therefore, there is no suggestion or motivation to make the proposed modification.

It is respectfully submitted that combining the Eek publication with the Depui patent would result in a single dosage form containing the combination of both omeprazole and diclofenac (as described in the Depui patent), in a blister pack card (as described in the Eek publication), rather than the packaging system of the present invention.

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The Examiner stated that the "claim limitations in claims 1-3 and 19 drawn to the types of dosage forms to be packaged therein essentially amount, in the view of the Examiner, to a recitation of the future intended use of the claimed invention."

It is noted that limitations in a claim following the word "comprising" are limitations and not mere recitations of future intended use that must be considered in patentability analysis.

Removal of the obviousness rejection is respectfully requested.

The Examiner is also directed to new claim 21 which recites in part, a packaging system that is further limited to a one which "is perforated to allow the separation of at least one discreet dosage of said first drug and said second drug while leaving the remaining dosages intact to said drug packaging system." It is respectfully submitted that new claim 21 is also not anticipated or obvious in view of the cited prior art.

IV. <u>CONCLUSION</u>

In view of the arguments presented, it is respectfully submitted that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully Submitted,

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